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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,597	12/08/2000	Edgar B. Cahoon	BB1413 US NA	2801

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/732,597

Applicant(s)

CAHOON ET AL.

Examiner

Elizabeth F. McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 27-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

The amendment filed November 13, 2002 has been entered.

Claims 1-26 have been cancelled.

Claims 27-45 have been newly submitted.

Applicant's election with traverse of Group I and SEQ ID NO: 1 and 2, in Paper No. 8 is  
5 acknowledged.

Applicant's election without traverse of Group I and SEQ ID NO: 1 and 2, in Paper No.  
8 is acknowledged. The newly submitted claims are all drawn to the elected invention.

Claims 27-45 are examined on the merits.

Claim 34 is objected to for failing to further limit the subject matter of claim 33 on which  
10 it depends.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of  
15 matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and  
requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and  
20 process of making and using it, in such full, clear, concise, and exact terms as to enable any  
person skilled in the art to which it pertains, or with which it is most nearly connected, to  
make and use the same and shall set forth the best mode contemplated by the inventor of  
carrying out his invention.

Claims 27-45 are rejected under 35 U.S.C. 101 because the claimed invention is not  
supported by either a specific asserted utility, a credible asserted utility or a well established  
utility.

Claims 27-45 are drawn to a polynucleotide sequence that encodes the amino acid sequence of SEQ ID NO:1 encoding SEQ ID NO: 2, and the specification states that this sequence is a delta-4-16:0-ACP desaturase. However, the specification does not provide any evidence to support the claim that this sequence would have delta-4-16:0-ACP desaturase activity. While the specification discloses methods for transforming plants with sequences and analyzing for seed oil fatty acids, there is no indication that any of these plants were transformed with the sequence that is claimed. In addition, the specification discloses that SEQ ID NO: 2 has 73.8% homology to a from delta-4-16:0-ACP desaturase coriander. However, one cannot conclude that homologous sequences have the same functional activity (as stated below). The only specific utility provided for the claimed sequence is for use as a delta-4-16:0-ACP desaturase. However, this utility is not supported by the mere disclosure of SEQ ID NO: 1 and 2 and unsupported assertion that it has delta-4-16:0-ACP desaturase activity.

Claims 27-45 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 27-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 27-45 are drawn to a polynucleotide sequence that encodes the amino acid sequence of SEQ ID NO: 1 and to sequences encoding SEQ ID NO: 2 or at least 75% identical to SEQ ID NO: 2, and encoding a delta-4-16:0-ACP desaturase. However, the specification does not provide any evidence to support the assertion that this sequence would have delta-4-16:0-ACP desaturase activity, as stated above. Even though a sequence was known that has similarity to the claimed sequence, it is well established that sequence similarity is not sufficient to determine functionality of a DNA coding sequence. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions" (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that "there are numerous cases in which proteins of very different functions are homologous" (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that "most homologs must have different molecular and cellular functions" (see the second full paragraph of the second column of page 132, for example). Furthermore, Bork (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a specific activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known, one cannot conclude on this basis alone that these sequences also will encode a protein having said activity without additional evidence of the functionality or more knowledge of the particular structural features that are required for conferring this function. Therefore, it would require undue experimentation to establish how to use the claimed sequence, given the uncertainty of predicting the activity of an enzyme from a specific amino acid sequence, as stated above; the absence of guidance with regard to what amino acid sequences would confer delta-4-16:0-ACP desaturase activity; the lack of working examples that the claimed sequence encodes a delta-4-16:0-ACP desaturase; and given the high level of skill in the art and the state of the prior art, which did not teach what structural elements are required to obtain a sequence encoding a delta-4-16:0-ACP desaturase gene.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 27, 34 and 36-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahoon et al (PNAS 89:11184-11188, 1992).

The claims are drawn to a polynucleotide encoding a delta-4-16:0-ACP desaturase having at least 75% identity to SEQ ID NO: 2, and a recombinant nucleic acid and vector comprising said polynucleotide and said vector transformed into a plant for the production of petroselinic acid.

Cahoon et al teach a polynucleotide encoding a delta-4-16:0-ACP desaturase having 75% identity to SEQ ID NO: 2 (see the attached sequence alignment), and a recombinant nucleic acid and vector comprising said polynucleotide and said vector transformed into a plant for the production of petroselinic acid (see the abstract, at least).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

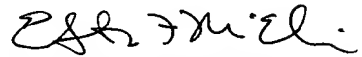
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

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Any inquiry of a general nature or relating to the status of this application should be directed to the legal analyst, Tiffiany Tabb, whose telephone number is (703) 605-1238, or to the Group receptionist whose telephone number is (703) 308-0196.

5 Elizabeth F. McElwain, Ph.D.  
January 23, 2003

  
**ELIZABETH F. McELWAIN**  
**PRIMARY EXAMINER**  
**GROUP 1600**